UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,681	09/29/2003	Stuart Peirson	4586-4001	5505

27123 7590 09/15/2006

MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER	
AGRAWAL, RITESH	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,681	PEIRSON ET AL.	
	Examiner	Art Unit	
	Ritesh Agrawal	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-14,22-33 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-21,34,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/01/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Amendments

1. Applicant's election with traverse of invention II (claims 15-21 and 34) in the reply filed on 08/25/06 is acknowledged. The traversal is on the ground(s) that there is no search burden involved in searching the different inventions, where, in particular, no search burden exists in commonly searching inventions I and II since both inventions are classified in the 702 class. This is not found persuasive because each of the three groups is separately classified, with groups I and II classified in different subclasses. As a result, a search of art against all three inventions would require three separate class/subclass searches. Furthermore, searches of all groups require a different search strategy where the search fields are distinct. The shared class of inventions I and II does not obviate this search burden.

Claims 1-14, 22-33, and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/25/06.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's amendments filed 09/29/03 and 08/25/06 are acknowledged and entered. In light of applicant's amendments, claims 1-37 are pending with the application. Claims 15-21, 34, and 36-37 are currently under consideration.

Sequence Compliance Rules

2. This application contains sequence disclosures that are encompassed by the definitions for the nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a)(2). Such sequence is present on page 13 of the specification. However, this application fails to comply with the requirements of 37 CFR 1.821 (d) because the sequences are not followed by a sequence identifier (SEQ ID NO: X). Applicants are reminded that it is required that SEQ ID numbers be amended into the specification at each sequence. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g).

Drawings

3. The drawings are objected to because they contain multiple figures on a single sheet. If applicant wishes to retain the multiple figures on a single sheet, they should be labeled 1A, 1B, 1C, etc. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

4. The Information Disclosure Statement filed 04/01/04 has been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Specification

5. The disclosure is objected to because of the following informalities:

The use of the trademarks MACVECTOR, RETROSCRIPT, and FASTPREP has been noted in this application. These trademarks can be found, for example, on page 12 of the specification. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 15-21, 34, and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "the cycle number" in line 7 and the cycles number in line 9. There is insufficient antecedent basis for these limitations in the claim.

Claim 19 recites the limitation "the log" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the log of the signal" in line 7. There is insufficient antecedent basis for this limitation in the claim. It is unclear at which of the two cycles of line 5 the signal is to be measured.

Claim 21 recites the limitation "the number of points" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 recites the limitation "the coefficient of determination" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 34 recites the limitation "the calculation" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 15, to which it refers, discloses multiple “calculations.” It is therefore unclear as to which of these calculations the phrase of claim 34 refers.

Claim 37 recites the limitation "the measuring unit" in line 4. There is insufficient antecedent basis for this limitation in the claim.

The term "substantially linear" in claims 15 and 37 is a relative term which renders the claim indefinite. The term "substantially linear" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 15-18, 34, and 36-37 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Ward et al. (US Patent Publication # 2003/0044826) with a priority date of August 21st, 2001.

The claims are drawn to a system for analyzing data from a polymerase chain reaction. The system includes:

a) A memory

b) A unit for calculating a logarithm of the signal

c) A reaction efficiency calculator

d) A selector for selecting a set of cycles

e) An estimator for estimating slope

Ward et al. disclose a system for quantifying DNA from a polymerase chain reaction (abstract, lines 1-3). Their system includes memory (see, for example, figure 8, module 830). Their system calculates a logarithm of the signal (see, for example, figures 1, 2, or 7a). They disclose calculating amplification efficiency (see paragraph 67, lines 9-10) and provide an equation for the calculation (paragraph 85, lines 2-3). They disclose selecting "threshold cycles" (paragraph 83, lines 6-8). They also disclose that their system estimates slopes (claim 23).

With respect to claim 16 with the additional limitation that the signal is a fluorescent signal, Ward et al. disclose their use of fluorescence (see, for example, claim 25).

With respect to claim 17 with the additional limitation that the estimator carry out linear regression, Ward et al disclose the limitation (see, for example, paragraph 82, line 1).

With respect to claim 18, with the limitation that the estimator average the difference of the signal between adjacent cycles, performing a linear regression is a method of average the difference between data points and therefore Ward et al. disclose the limitation of claim 18 as cited above for claim 17.

With respect to claim 34 with the additional limitation that the calculations be carried out in real-time, while the reaction proceeds, Ward et al. disclose at least one embodiment of their invention that is able to carry out calculations in real-time. They disclose that their data processing module, which carries out the calculations, can receive data directly from the collection module (see paragraph 91, lines 1-4) which receives data in real-time, while the reaction module is in operation (see paragraph 89, lines 4-6).

With respect to claim 36, with the additional limitation of a measuring unit, Ward et al. disclose a data collection module that detects and measures fluorescence (see paragraph 89, lines 1-4).

With respect to claim 37, with the additional limitation that the system be applicable to multiple samples, Ward et al. disclose that the system can be run on a plurality of reactions by averaging results from the plurality of reactions (paragraph 7, lines 11-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. as applied to claims 15-18 and 36-37 above, and further in view of Peirson et al. (Nucleic Acids Research, Vol. 31, pages 1-7, July, 2003).

The claims are drawn to the method of claim 15 with the additional limitation of a selector wherein the set of cycles is centered around the cycle with a fluorescent level closest to the average of the noise and saturation levels.

Ward et al. disclose a system with the limitations of claim 15 as cited above.

However, Ward et al. do not disclose the selector of claim 19 wherein the set of selected cycles is centered around the cycle with a fluorescent level closest to the average of the noise and saturation levels.

Peirson et al. disclose a selector wherein the selected cycles are centered around the cycle(s) with fluorescent levels closest to the average of the noise and saturation levels (page 3, 1st paragraph, lines 1-2 and equation therebelow). While Peirson et al. do not explicitly disclose that this midpoint would represent a single cycle for an odd number of total cycles or two cycles for an even number of total cycles, by definition, the midpoint for an odd number of cycles is a single cycle and the midpoint for an even number of cycles is two cycles.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of Peirson et al. to use it along with the system of Ward et al. One of ordinary skill in the art would have been motivated to modify the method of Peirson et al., because the system of Ward et al. provides an integrated system in which to carry out all the steps from the acquisition of PCR data, to obtaining a final quantitation of DNA. In providing a single, integrated, automated system, the combined system would eliminate the need for initial analysis of amplification data via other means (see, for example, the need for initial analysis via SDS 1.7, Peirson et al. page 2, 2nd paragraph, lines 1-3). In so doing, it would allow for the entire analysis in a user-independent manner (Ward et al., paragraph 91, lines 12-15), which could improve the performance and accuracy of the calculation (Ward et al., paragraph 40, lines 5-6). Hence, by integrating the methodology of Peirson et al. into

the system of Ward et al. one would obtain better results and the analysis would take less of their time.

With respect to claim 20, Peirson et al. disclose linear regression around the midpoint (page 3, 2nd paragraph, lines 6-8).

With respect to claim 21, in the absence of an explicit definition for the term coefficient of determination, it will be interpreted to mean the best combination of slope and R^2 values. Ward et al. disclose selecting points for analysis based upon maximizing these parameters (see, for example, claim 23).

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal RA 9/13/06